K053440

DEC 30 2005

APPENDIX D
510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

510(K) SUMMARY AS DESCRIBED IN 21 CFR 807.92

Manufacturer:

AGA Medical Corporation
682 Mendelssohn Avenue
Golden Valley, MN 55427

Establishment Registration:

2135147

Contact:

Amanda Johnson, Regulatory Affairs Manager
(888) 546-4407 phone, (763) 513-9226 fax
ajohnson@amplatzer.com (e-mail)

Date:

December 8, 2005

Product Trade Name:

AMPLATZER® Sizing Balloon II

Common/Usual Name:

Temporary Occluding Catheter

Classification Name:

Catheter, Intravascular Occluding, Temporary
21 CFR 870.4450 (Product Code MJN)

Predicate Devices:

The AMPLATZER® Sizing Balloon II is equivalent in design to currently marketed balloon catheters for temporary vessel occlusion:

- AMPLATZER Sizing Balloon (K993248)
- Numed PTA-OS Sizing Balloon (K003320)

Performance Standards:

No performance standards have been developed under section 514 for this device.

Device Description:

The AMPLATZER® Sizing Balloon II is a triple lumen balloon catheter with three (3) radiopaque marker bands located inside the balloon to allow for radiographic measurement. The center of the balloon contains a pair of marker bands 0.4mm apart (inside to inside), and one (1) marker band 15 mm proximal of that pair.

Intended Use:

The AMPLATZER® Sizing Balloon II is intended for use in those patients with cardiovascular defects wherein accurate measurement of the defect is important to select the appropriately sized occluder device.

Summary of Non-Clinical Testing:

The following non-clinial tests were performed on the AMPLATZER® Sizing Balloon II:

- Inflation time
- Deflation time
- Burst volume
- Bifurcation separation

- Tip separation
- Sidearm stopcock to tube separation
- Sidearm luer to tube separation
- Marker band placement
- Biological testing

Conclusions:

The currently marketed AMPLATZER Sizing Balloon (K993248) has been modified to include design modifications, a new supplier and an additional catheter size (18mm). This modified product has been given the trade name AMPLATZER Sizing Balloon II. The modifications made did not alter the intended use or fundamental scientific technology of the predicate product.

The AMPLATZER® Sizing Balloon II is substantially equivalent to currently marketed balloon catheters used for temporary vessel occlusion, which include the AMPLATZER Sizing Balloon and Numed PTA-OS Sizing Balloon.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 3 0 2005

AGA Medical Corporation
c/o Ms. Amanda Johnson
Regulatory Affairs Manager
682 Mendelssohn Avenue
Golden Valley, Minnesota 55427

Re: K053440
Trade Name: Amplatzer® Sizing Balloon II
Regulation Number: 21CFR 870.4450
Regulation Name: Sizing Balloon
Regulatory Class: II (two)
Product Code: MJN
Dated: December 8, 2005
Received: April 15, 2005

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: AMPLATZER® Sizing Balloon II

Indications for Use:

AMPLATZER® Sizing Balloon II is indicated for use in those patients with cardiovascular defects wherein accurate measurement of the defect is important to select the appropriately sized occluder device.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Bram D. Zuckerman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K053440